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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,568	01/04/2002	Yasuhiko Shimizu	56871 (70958)	9246

21874 7590 05/10/2004

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EXAMINER	
LANDREM, KAMRIN R	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,568	SHIMIZU, YASUHIKO	
	Examiner	Art Unit	
	Kamrin R. Landrem	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,5 are rejected under 35 U.S.C. 102(b) as being anticipated by Hansson et al (USPN 5,656,605).

With reference to Figure 1, Hansson discloses a polyglycolic acid (2:53-55) artificial tube 2 having a lumen containing fibrous collagen (3:17-22) bodies 6 made of laminin (2:21-23) and other various growth factors (2:56-58).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansson in view of Buscemi et al (USPN 5,769,883).

Hansson, as discussed above, discloses the artificial nerve tube as claimed however Hansson fails to disclose the coating and pore size of the mesh. Buscemi teaches a biodegradable tubular body composed of polyglycolic acid, collagen (6:13) and laminin (3:49) having a

collagen based inner and outer coating (6:24-33) and a pore size of 0.1-30 microns (6:66-67) that provides mechanical support and a uniform release of drugs to the surrounding area. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the nerve tube as disclosed by Hansson to incorporate the coating and pore size of the tubular structure as taught by Buscemi in order to provide an artificial nerve tube that is bioabsorbable has improved biocompatible properties due to the coating.

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansson in view of Silver et al (USPN 4,703,108).

Hansson, as discussed above, discloses the artificial nerve tube as claimed however Hansson fails to disclose the method of producing the tube. Silver teaches the method for producing a biodegradable matrix comprising the steps of introducing a hydrochloric acid to dissolve the laminin coated (8:45-50) collagen, freezing the solution before freeze drying the solution (7:60-68) and then further crosslinked (9:9-16) to provide a controlled release to internal wounds requiring that only one surgery be performed. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have composed the nerve tissue by the method as taught by Silver in order to produce a biodegradable matrix that allows for controlled release of drugs, growth factors, etc. and only requires one surgery.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,4,5, and 6 of U.S. Patent No. 6,090,117. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims describe the structure of an artificial nerve tube made from a bioabsorbable mesh having a collageneous coating and fibrous collagen bodies filled with laminin.

Response to Arguments

Applicant's arguments filed 2/23/04 have been fully considered but they are not persuasive. The applicant's arguments are narrower than the claims. With regards to applicant's arguments concerning the additional "guiding elements" of Hansson it is noted that the transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997). The same applies with respect to applicant's arguments concerning the extra step taught by Silver, which includes introducing a crosslinking agent. The

method recited by the applicant includes the term "comprising" therefore the claim is also open ended and additional steps such as those taught by Silver are proper.

The applicant's arguments with regards to the unique fibrous structure and periodic filament structure are unpersuasive because these features are not recited in the claims. Contrary to the applicant's arguments, the examiner did provide motivation in the previous office action for the teachings of Buscemi and Silver. Buscemi provides structural support and a strengthened matrix (3:45-51) while Silver provides a biodegradable polymer that offers the advantage of controlled release to internal wounds and only requires one surgical procedure (1:29-32). Finally the double patenting reject still stands because contrary to applicant's arguments regarding the lack of laminin in the voids of Shimzu, Shimzu recites in Claim 1 that laminin is present within the cavities (13:9).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kamrin Landrem
Examiner
AU 3738

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